

**REMARKS**

Applicants initially wish to thank Examiners Thomas and Gilligan for the interview with co-inventors Drs. Michael Hagen and Walton Sumner, and the undersigned (Applicants' representatives) on November 18, 2003. During that interview, the Office Action dated June 5, 2003 was discussed, and arguments were presented regarding the distinguishing features of the present invention vis-à-vis the applied references cited in the Office Action. In the Interview Summary, the Examiners agreed that Applicants' proposed amendments appeared to distinguish over the applied prior art.

After entry of the amendment, claims 2-43, 46-48 and 52-66 are pending. Claims 37-41 and 46-48 and 52 are independent, and claims 2-36, 42-43, and 53-66 are dependent. Claims 2-36 and 53-66 (directly or indirectly) depend from claim 40, and claims 42-43 depend from claim 41.

No new matter is added. Favorable reconsideration and allowance of the claims are requested.

Claims 41-43 and 46 are rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,006,987 to Harless (Harless).

Claims 40, 2-25, 27, 29, 34, 37-39 and 48 are rejected under 35 U.S.C. §103(a) as being obvious over Harless in view of U.S. Patent No. 5,882,206 to Gillio (Gillio).

Claims 28, 30-33, 35 and 36 are rejected under 35 U.S.C. §103(a) as being obvious over Harless in view of Gillio, and further in view of U.S. Patent No. 5,657,255 to Fink et al. (Fink).

Claims 26, 47 and 52 are rejected under 35 U.S.C. §103(a) as being obvious over Harless in view of U.S. Patent No. 6,108,635 to Herren et al. (Herren).

Applicants note that the references to Gillio, Fink and Herren can be antedated with a 37 CFR 1.131 affidavit. Accordingly, any amendments presented herein should not be construed as narrowing amendments with respect to any of these references.

### **The Claimed Invention**

One embodiment of the claimed invention (claim 37) is directed to a computer simulation and evaluation system for simulating, for example, "interventions, to a patient having a health state, by a user, and for evaluating the interventions." The system comprises a knowledge database that has a plurality of patient health characteristics. The system accesses a profile of a user, including one or more areas where the user's medical knowledge requires at least one of simulation and requires evaluation. The system defines a test area in response to the user profile. In addition, the system dynamically generates a patient history that is tailored to the user profile. The patient history includes the patient's age, gender, and age of onset of medical condition. Further, the medical condition is one of a plurality of medical conditions available within the knowledge database. Finally, after the user provides an input to the system, the system evaluates the user responsive to the user's input.

This and other embodiments of the present invention can be used repeatedly, with numerous users, to evaluate users' medical knowledge. As discussed on page 34 of the specification, the present invention offers so many cases that an examinee (current or future) gains little advantage with regard to test content by observing other examinees or examinations. By contrast, as discussed at least on pages 23 and 24 of the specification, known patient-user medical simulations are "hard-wired" into the system, thereby rendering them unsuitable for widespread use in testing as they typically provide a single or very limited number of patient scenarios.

### **U.S. Patent No. 5,006,987 to Harless**

With regard to Harless, column 4, lines 17-30 indicate that the interactive medical drama concerns a single patient (Frank Hall), with a single medical condition ("weakness and abdominal pain following an episode of vomiting blood two days earlier"). As column 3, lines 27-31, and claims 1, 6, 7, 19 and 24 indicate, the drama is "prerecorded." Consequently, and in contrast to the claimed invention, Harless does not consider, for example, the medical knowledge of the user. With Harless, it does not matter what the profile, or medical knowledge, of the user is, particularly since all users will encounter the same patient with the same medical condition. Nor is the patient's medical history, for example, dynamically generated, based upon a user's profile.

**U.S. Patent No. 5,882,206 to Gillio**

With regard to Gillio, column 5, lines 20-58 indicate that the virtual surgery system can be used to perform a “practice run” for an actual surgery (a virtual surgery), or can be used in connection with a real surgery. Gillio discloses that particular patient image data “can be chosen by the surgeon prior to the virtual surgery operation.” (emphasis added). Gillio is thus concerned with a user possessing specific medical/surgical skills, who may want to perform a virtual and/or real surgery. Consequently, without conceding that Gillio discloses any of the limitations of the present invention, Gillio does not use, or even consider, for example, a user’s profile to dynamically generate patient scenarios for the purpose of selecting a testing area that is used to evaluate the user. More generally, Gillio is not at all concerned with, for example, clinical scenarios, but is particularly focused on surgical settings.

**U.S. Patent No. 5,657,255 to Fink et al.**

Fink is directed to creating an executable model of a biological system that can be used to provide insight into phenomena at the cellular, or subcellular level, as well as phenomena at the patient, organ and system levels. (Abstract). With regard to clinical trials, column 13, lines 1-20 of Fink state that, once created, the “model can be run using various patient and treatment characteristics to determine the patients that would benefit most from specific treatments and those patients that may experience problems in the study.” Thus, in contrast to the present invention, which is concerned, for example, with testing a particular user’s medical problem-solving abilities, Fink is concerned with screening patients who may benefit from or be adversely affected by a particular treatment. Fink thus has little, if anything, to do with the present invention. Without conceding that Fink discloses any of the features of the present invention, Fink does not generate a patient and patient history for purposes of testing a user’s medical problem-solving skills. Nor does Fink consider the user’s area(s) that requires evaluation for any purpose, let alone for purposes of generating a patient history.

**U.S. Patent No. 6,108,978 to Herren et al.**

Herren is directed to a system and computer assisted methodology that supports development of new medical interventions for diseases (see, e.g., Abstract, claim 1). Without conceding that Herren discloses any of the limitations of the present invention, Herren is not concerned with testing a user's medical problem-solving skills. Accordingly, like Fink, Herren does not, for example, generate a patient and patient history for such a purpose. Nor does Herren consider, for example, the user's area(s) that requires evaluation for any purpose, let alone for purposes of generating a patent history (which Herron does not do).

**The §102(b) Rejections - Claims 41-43 and 46.**

Claims 31-43 and 46 are rejected as anticipated by Harless. Applicants respectfully traverse this rejection.

Harless is directed to "an interactive audiovisual system" (claims 1 and 6), and operates in a fundamentally different way than the claimed invention. Without conceding that Harless discloses any of the elements of the present invention, Harless does not utilize or consider, for example, a profile of the user to dynamically generate a patient having a medical history that is tailored to test the user. Instead, Harless presents the user with a single patient having a particular medical condition. Consequently, Harless does not, for example, dynamically generate a patient to test the medical skills of the user.

Without conceding that Harless discloses any of the limitations in claims 41-43 and 46, Harless further does not teach or suggest, let alone disclose, a dynamically generated patient history that comprises "a patient age, gender, and age of onset of medical condition," as recited in the claimed invention. Accordingly, since Harless does not dynamically generate a patient history, such patient history cannot extend "back in time to a state of normal patient health," as recited, for example, in the claim 43. Moreover, the medical condition of the patient in Harless is not "one of a plurality of potential medical conditions," let alone one of a plurality of medical conditions that have been "dynamically" generated, each as recited in the claimed invention. Instead, and as has been noted, Harless merely presents to all users, in a prerecorded, static manner, a single patient with a single medical condition.

For at least these reasons, Applicants submit that Harless does not anticipate the claimed invention. Accordingly, at this time Applicants believe the above differentiators are sufficient and exemplary, without providing and exhaustive list of differentiators. Applicants request

that independent claim 41, dependent claims 42-43, and independent claim 46 be passed to issue.

**The §103(a) Rejections.**

**a. Claims 37-40, 2-25, 27, 29, and 34.**

Claims 37-40, 2-25, 27, 29, 34 are rejected under 35 U.S.C. §103(a) as being obvious over Harless in view of Gillio. Applicants respectfully traverse this rejection.

In contrast to Harless, which does not utilize or consider, for example, a profile of the user to dynamically generate a patient having a medical history that is tailored to test the user (as well as other features), claims 37-40 of the present invention utilize and recite in combination that the system accesses a profile the user. In further contrast to Harless, which merely presents a single patient with a single medical condition, the claimed invention utilizes, and recites in combination, the user profile to perform the step of “dynamically generating a patient history” that is tailored to the user profile, and that comprises “a patient age, gender, and age of onset of medical condition.” Still further in contrast to Harless in this regard, the claimed invention provides a medical condition of the patient that “is one of a plurality of medical conditions.”

The Examiner’s rejection of claims 37-40 has now been rendered moot. Applicants nevertheless note that Applicants disagree with the Examiner’s interpretation of Gillio with respect to the claimed invention. The Examiner concedes that “Harless does not explicitly teach accessing a profile for said user.” On page 4 of the Office Action, the Examiner goes on to state, however, that “Gillo (sic) teaches accessing a user profile for a user being evaluated on interaction with a simulated patient (see column 13, lines 36-41).” However, column 13, lines 36-41 of Gillio expressly refer to Figure 13, step 814, which clearly occurs after step 804, where the model of the anatomical space is received. Accordingly, Gillio actually teaches away from the claimed invention, which utilizes a user profile to dynamically generate “a patient that is tailored to the user profile, comprising a patient age, gender, and age of onset of medical condition.” In view of the foregoing, Applicants emphasize that Gillio, in fact, teaches away from the claimed invention.

Accordingly, when each of claims 37-40 are considered for the independent combination of features recited therein, Applicants respectfully submit that claims 37-40 are patentable over the prior art.

Claims 2-25, 27, 29, and 34 recite allowable subject matter by virtue of their dependency from claim 40, as well as additional features recited in each of these dependent claims, when each is interpreted in combination and as a whole.

**b. Claim 48**

Claim 48 also recites in combination the step of “dynamically generating, responsive to said user profile, a medical history for said simulated patient.” Claim 48 also recites in combination that the subject matter on which the user is evaluated “is determined by said user profile.”

In view of the foregoing general discussion regarding independent claims 37-40, and the additional limitation recited in combination in claim 48, Applicants submit that Harless and Gillio do not teach at least this combination of features of the claimed invention, recited in claim 48.

**c. Claims 28, 30-33, 35 and 36**

Claims 28, 30-33, 35 and 36 recite allowable subject matter by virtue of their dependency from independent claim 40. In addition, each of these claims recite additional features, which when interpreted in combination, are patentable over the prior art.

For example, with respect to claim 28, the Examiner now agrees that Fink does not disclose anything with regard to entity relationship models, as that phrase is used in the present invention. For example, as indicated on page 39 of the specification, in “an entity-relationship diagram, entities usually represent things (nouns). The relations (verbs) illustrate how the entities interact.” In contrast, the “Knowledge Diagram” of Fink, shown in Figure 7, uses a “+” or a “-” to indicate whether a particular interaction is enhanced or inhibited, respectively (column 8, lines 7-16). This is clearly different from an “entity relationship” mentioned above (and in the specification and claims of the present patent application).

With regard to claim 30, for example, the Examiner also now agrees that Fink does not disclose anything with regard to parallel networks, as that phrase is used in the present invention. For example, page 77 of the specification states:

A parallel network health network lists transitions that occur among an exhaustive set of mutually exclusive health conditions occurring in one body part. For instance, the left knee of a patient exists in one of the health conditions in the osteoarthritis network. The right knee also exists in one of these conditions, but not necessarily the same condition found in the left knee. The patient simultaneously exists with the one condition in a gastric ulcer network, a weight network, and numerous other networks.

In contrast to Applicants' claimed parallel health networks, column 12, lines 4-8 of Fink, cited by the Examiner, refers to how a jagged edge on each of two models represents the changing and synthesizing of information common to the two models. This, of course, has nothing to do with "parallel health networks," as recited in the claimed invention.

Applicants reserve the right, as may be necessary, to specify additional differentiators between the teaching of Fink with respect to the claimed invention.

#### **d. Claims 26, 47, and 52**

Claim 26 is allowable by virtue of its dependency from claim 40, as well as additional limitations recited therein, when interpreted in combination.

Claim 47 recites in combination the step of "dynamically generating a medical history for said patient, wherein generating said medical history comprises iterating from a current medical condition backward in time through at least one precursor health state to a normal health state." Claim 47 also recites in combination that the "the medical condition is one of a plurality of potential medical conditions."

With regard to the "dynamically generating" step, on page 14 of the Office Action the Examiner agrees that Harless does not explicitly teach that generating a patient medical history comprises "iterating from said first target health state backward in time through at least one precursor health state to an initial health state." The Examiner takes the position,

however, that “Herren teaches generating a medical history for a simulated patient by iterating from a first target health state backward in time through at least one precursor health state to an initial health state (column 7, lines 42-46).” However, as discussed during the November 18, 2003 interview and as agreed by the Examiner, column 7, lines 42-46 do not disclose these features of the claimed invention. In particular, this passage expressly states that “a Patient History module receives user inputs of the specific patient attributes.” (emphasis added). The fact that the Patient History merely **receives** information is further supported by, for example, Figure 27, column 41, lines 30-55, and claim 25. Accordingly, insofar as the Patient History module disclosed in Herren passively receives information, Herrin cannot in any way be considered to teach or suggest, for example, Applicants’ claimed limitation of “dynamically generating a medical history for a patient, wherein generating said medical history comprises iterating from a current medical condition backward in time through at least one precursor health state to a normal health state.” (emphasis added). Finally, Applicants have previously discussed how Harless does not teach or suggest that “the medical condition is one of a plurality of potential medical conditions,” as well as other features of the present invention which are absent from Harless.

Claim 52 recites in combination, for example, “selecting subject matter on which to evaluate said user from a plurality of subject matter.” Claim 52 also recites in combination the step of “dynamically generating a first problem environment, wherein said first problem environment is determined by said subject matter.” In addition, claim 52 recites in combination the step of “dynamically generating a history of said first problem environment, wherein generating said history comprises iterating from said first problem environment backward in time through at least one precursor situation to an initial situation.”

As has been discussed, Harless does not teach or suggest the step of “selecting subject matter on which to evaluate said user from a **plurality of subject matter**,” particularly insofar as Harless discloses a single patient having a particular medical condition. (emphasis added). In addition, for the reasons discussed above with regard to claim 47, neither Harless nor Herren teach or suggest, let alone disclose, the steps of “dynamically generating a first problem environment, wherein said first problem environment is determined by said subject matter,” or “dynamically generating a history of said first problem environment, wherein generating said history comprises iterating from said first problem environment backward in

time through at least one precursor situation to an initial situation." Further, neither Harless or Herren disclose other features of the present invention.

Accordingly, Applicants respectfully submit that the combination of limitations recited in claims 26, 47 and 52 are patentable over the prior art, when interpreted as a whole.

### CONCLUSION

For all the reasons advanced above, Applicants respectfully submit that the rejections have been overcome and must be withdrawn. Accordingly, Applicants request that the application be passed to issue.

In view of the foregoing, Applicants submit that the cited prior art does not disclose or suggest the combination of features recited in the claims. Applicants do not concede that the cited prior art shows any of the elements recited in the claims. However, Applicants have provided specific examples of elements in the claims that are clearly not present in the cited prior art.

Applicants strongly emphasize that one reviewing the prosecution history should not interpret any of the examples Applicants have described herein in connection with distinguishing over the prior art as limiting to those specific features in isolation. Rather, Applicants assert that it is the combination of elements recited in each of the claims, when each claim is interpreted as a whole, that is patentable. Applicants have emphasized certain features in the claims as clearly not present in the cited references, as discussed above. However, Applicants do not concede that other features in the claims are found in the prior art. Rather, for the sake of simplicity, Applicants are providing examples of why each of the claims described above are distinguishable over the cited prior art.

**AUTHORIZATION**

The Commissioner is hereby authorized to charge any additional fees which may be required for this Amendment, or credit any overpayment to deposit account no. 08-0219.

In the event that an extension of time is required, or which may be required in addition to that requested in a petition for an extension of time, the Commissioner is requested to grant a petition for that extension of time which is required to make this response timely and is hereby authorized to charge any fee for such an extension of time or credit any overpayment for an extension of time to deposit account no. 08-0219.

Respectfully submitted,

HALE AND DORR LLP

Gregory S. Discher for  
Irah H. Denner  
Registration No. 35,120

Gregory S. Discher  
Gregory S. Discher  
Registration No. 42,488

1455 Pennsylvania Avenue, N.W.  
Washington, D.C. 20004  
TEL 202.942.8585  
FAX 202.942.8484  
Date: 12/05/03